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*Counsel for Plaintiffs*  
*ALLERGAN, INC. and ALLERGAN SALES, LLC.*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ALLERGAN SALES, LLC and ALLERGAN, INC.

Plaintiffs,

v.

SANDOZ, INC. and ALCON LABORATORIES,  
INC.

Defendants.

Civil Action No. \_\_\_\_\_

**Jury Trial Demanded**

*Electronically Filed*

**PLAINTIFFS ALLERGAN SALES, LLC'S AND ALLERGAN, INC.'S COMPLAINT  
AGAINST  
SANDOZ, INC. AND ALCON LABORATORIES, INC.**

Plaintiffs Allergan Sales, LLC and Allergan, Inc. (collectively "Allergan" or "Plaintiffs")  
by their attorneys, Fish & Richardson P.C. and Walsh Pizzi O'Reilly Falanga, for their  
complaint against Defendants Sandoz, Inc. ("Sandoz") and Alcon Laboratories, Inc. ("Alcon,"  
together with Sandoz, "Defendants") alleges as follows:

**The Nature of the Action**

1. This is an action for infringement of United States Patent No. 9,770,453 (the  
"453 patent") under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under

28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(b) and (c) relating to Allergan's commercially successful product, Combigan®.

### **The Parties**

2. Allergan Sales, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, New Jersey, 07940.

3. Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, New Jersey, 07940.

4. On information and belief, defendant Sandoz, Inc. is a Colorado corporation and a division of Novartis Corporation. Novartis Corporation is located at One Health Plaza, East Hanover, NJ 07936, and Sandoz's principal place of business at 100 College Road West, Princeton, New Jersey 08540.

5. On information and belief, defendant Alcon Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6201 South Freeway, Fort Worth, TX 76134-2099, and a registered agent at 211 E. 7th Street, Suite 620, Austin, TX 78701-3218.

6. On information and believe, Sandoz and Alcon are related corporate entities with respect to generic pharmaceuticals. On further information and belief, Sandoz and Alcon each originally filed separate abbreviated new drug applications ("ANDAs") seeking to manufacture generic copies of Allergan's Combigan®. On further information and belief, in approximately 2011, Sandoz and Alcon merged their ANDAs into ANDA No. 91-087, and are working in concert to achieve final approval of their merged ANDA.

7. On information and belief, Defendants are in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial jurisdiction.

### **Jurisdiction and Venue**

8. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq* and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

9. This Court has personal jurisdiction over Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein. Upon information and belief, Sandoz has a place of business at 100 College Road West, Princeton, NJ 08540, and is registered to do business in New Jersey. Upon information and belief, Sandoz regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Upon information and belief, Sandoz derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Allergan has been injured in New Jersey because of Defendants' ANDA filing and the causes of action Allergan raises here, as alleged herein.

10. This Court has personal jurisdiction over Alcon by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein. Upon information and belief, Alcon's parent corporation, Novartis, has a place of business at One Health Plaza, East Hanover, NJ 07936. Alcon is registered to do business in New Jersey. Upon information and belief, Alcon regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Upon information and belief, Alcon derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of

conducting business within New Jersey. Allergan has been injured in New Jersey because of Defendants' ANDA filing and the causes of action Allergan raises here, as alleged herein.

11. Venue is proper in this Court under 28 U.S.C. § 1400(b).

12. Venue is proper in this District under 28 U.S.C. § 1400(b) because Sandoz "committed an act of infringement" in the district and has a "regular and established place of business" in this district. Sandoz submitted its ANDA No. 91-087 pursuant to 505(j)(2)(B)(ii) of the FDCA, and, upon receiving approval of its ANDA, will manufacture, sell, offer to sell, and/or import Defendants' proposed generic brimonidine/timolol ophthalmic solution in the United States, including in this district. Thus, Sandoz has committed an act of infringement in this district. Sandoz also has a "regular and established place of business" in this district. Sandoz has a principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5003732).

13. Venue is proper in this District under 28 U.S.C. § 1400(b) because Alcon "committed an act of infringement" in the district and has a "regular and established place of business" in this district. Alcon, in conjunction with Sandoz, submitted its ANDA No. 91-087 pursuant to 505(j)(2)(B)(ii) of the FDCA, and, upon receiving approval of its ANDA, will manufacture, sell, offer to sell, and/or import Defendants' proposed generic brimonidine/timolol ophthalmic solution in the United States, including in this district. Thus, Alcon has committed an act of infringement in this district. Alcon also has a "regular and established place of business" in this district. Alcon's parent corporation, Novartis, has a principal place of business at One Health Plaza, East Hanover, NJ 07936. Alcon is also licensed to do business with the

New Jersey Department of Health as a “Manufacturer and Wholesale[r]” of pharmaceuticals in the State of New Jersey (Registration Number 5004265).

14. The parties have previously litigated cases regarding Defendants’ ANDA No. 91-087 and related patents covering Allergan’s Combigan® in the Eastern District of Texas. After the Federal Circuit’s decision in *In re Cray*, 2017 WL 4201535 (Fed. Cir. Sept. 21, 2017), venue may not lie in that jurisdiction, and Sandoz and Alcon have challenged personal jurisdiction in the Eastern District of Texas in another case pending in that District. As a result, Allergan has filed this action in the District of New Jersey, where Defendant Sandoz has a place of business.

### **Background**

15. The ’453 patent, entitled “Combination of Brimonidine and Timolol for Topical Ophthalmic Use,” issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on September 26, 2017. A copy of the ’453 patent is attached to this complaint as Exhibit A.

16. Allergan, as assignee, owns the entire right, title, and interest in the ’453 patent.

17. Allergan is the holder of an approved New Drug Application (“NDA”) No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark.

18. In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration (“FDA”) eight patents that cover the approved formulation or methods of using the approved formulation of Combigan®. The listed patents are U.S. Patent Nos. 7,030,149, 7,320,976, 7,642,258, 8,133,890, 8,354,409, 8,748,425 9,474,751, and 9,770,453 (collectively, “the Listed Patents”). The FDA has published these eight patents in the Approved

Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

19. Combigan®, or approved methods of using Combigan®, are covered by at least one claim of the patents listed in the Orange book, including the ’453 patent.

20. On November 20, 2008, Sandoz submitted its ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell a generic version of Combigan®. Allergan filed suit against Sandoz in the Eastern District of Texas on April 7, 2009. (C.A. No. 2:09-cv-097). Sandoz’s ANDA No. 91-087 received tentative approval from the FDA on May 11, 2011.

21. In an August 22, 2011 opinion, the United States District Court for the Eastern District of Texas found that Defendants’ proposed generic versions of Combigan® infringed U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258, and that those patents were not invalid. *Allergan v. Sandoz*, 818 F. Supp. 2d 974 (E.D. Tex. 2011). The Court entered an injunction order on August 25, 2011, stating that Defendants were enjoined from manufacturing their proposed generic versions of Combigan® until the latest of the expiration dates of U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258.

22. On appeal, in a May 1, 2013 opinion, the Federal Circuit held that claim 4 of the ’149 patent is not invalid, declined to rule on the validity of the ’976 and ’258 patents, and ruled that the claims of the ’463 patent are invalid. In addition, the opinion affirmed the factual findings of this Court’s August 22, 2011 opinion. Defendants did not challenge the district court’s findings or conclusions on infringement on appeal. Thereafter, Defendants filed a petition for rehearing and rehearing *en banc*, which was denied on September 9, 2013, and a petition for a writ of certiorari to the Supreme Court, which was denied on March 31, 2014.

23. After the Federal Circuit denied Defendants' rehearing petitions, Defendants filed a motion for relief from Eastern District of Texas Court's judgment under Federal Rule of Civil Procedure 60 on September 17, 2013. The Court denied that motion on December 3, 2013, and the Federal Circuit affirmed the judgment denial without opinion. (Case No. 2:09-cv-97, D.I. 308; Case No. 2:09-cv-97, D.I. 316.)

24. On or about January 26, 2015, Allergan received a letter dated January 23, 2015, signed on behalf of Sandoz by Jean Domenico. The letter stated in part that "Sandoz has now amended its ANDA to include an additional certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) to U.S. Patent No. 8,748,425." The letter alleges that "the claims of the '425 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Product."

25. Included in the January 23, 2015 letter was an alleged "Detailed Statement" of the factual and legal basis for Sandoz's opinion that the claims of the '149 patent, '258 patent, '976 patent, and '425 patent are invalid and/or will not be infringed by the manufacture, use or sale of Defendants' Product.

26. Allergan filed suit in the Eastern District of Texas on March 9, 2015. (Case No. 2:15-cv-00347, Dkt. 1.) In a December 30, 2016 opinion, the Eastern District of Texas Court found the '149, '976, and '425 patents are not invalid, that the '149 and '976 patents are not infringed, and that the '425 patent is infringed by Defendants' ANDA No. 91-087. The Court therefore ordered that the effective date of any approval of Defendants' ANDA not occur before the expiration of U.S. Patent No. 8,748,425—i.e., April 19, 2022. The Court also ordered that the injunction previously issued, remains in full force and is in no manner limited or disturbed by this judgment.

27. Defendants appealed the Eastern District of Texas Court's judgment to the Federal Circuit. The Federal Circuit heard oral argument in the case on October 2, 2017, and the case remains pending.

28. Defendants' primary non-infringement argument on appeal, as it had been before the district court in the Eastern District of Texas, is that their proposed product, referred to as Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution (0.2%/0.5%), does not contain 0.5% timolol free base, despite of the name of the product on the label and the references to 0.5% timolol base throughout their ANDA. The claims of the '425 patent recite a method of treatment using a composition comprising 0.2% brimonidine tartrate and 0.5% timolol free base. Defendants acknowledge that their product is made using 0.2% brimonidine tartrate and 0.68% timolol maleate. Defendants further acknowledge that 0.68% timolol maleate contains 0.5% timolol, or 0.5% timolol base.

29. On September 26, 2017, the '453 patent issued. Unlike the claims of the prior patents, which generally recited methods of treating glaucoma or ocular hypertension by administering a composition comprising 0.2% w/v brimonidine and 0.5% w/v timolol (or, in the case of the '425 patent, 0.5% w/v timolol free base), the claims of the '453 patent recite a method of treating glaucoma or ocular hypertension by administering a composition comprising 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate. While Allergan continues to maintain that Defendants infringe the claims requiring 0.2% brimonidine or brimonidine tartrate and 0.5% timolol or timolol free base, Allergan obtained the new claims of the '453 patent specifically to address the district court's claim constructions of "brimonidine" and "timolol," which claim constructions Allergan continues to challenge, and Defendants' non-infringement arguments raised in the case that went to trial in October 2016.

30. The composition of Combigan®, the product covered by the claims, and of Defendants' proposed product under ANDA No. 91-087, is prepared by using 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate, which those of skill in this field have typically referred to as 0.5% w/v timolol, which is the concentration of timolol free base in 0.68% timolol maleate.

31. In filing their ANDA, Defendants have requested the FDA's approval to market a generic version of Allergan's Combigan® product throughout the United States, including in New Jersey.

32. Defendants' proposed label, like the proposed label for Combigan®, will refer to the product as "brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%," but will also note that the product is a "[s]olution containing 2 mg/mL brimonidine tartrate and 5 mg/mL timolol (6.8 mg/mL timolol maleate)."

33. On information and belief, the FDA has tentatively approved ANDA No. 91-087.

34. On information and belief, following FDA approval of ANDA No. 91-087, Defendants will sell the approved generic version of Allergan's Combigan® product throughout the United States, including in New Jersey.

### **Count I**

#### **(Infringement of the '453 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution)**

35. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

36. Defendants submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of their proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution throughout the United States.

By submitting this application, Defendants have committed an act of infringement of the '453 patent under 35 U.S.C. § 271(e)(2)(A).

37. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will constitute an act of infringement of the '453 patent.

38. On information and belief, Defendants became aware of the '453 patent no later than the date on which that patent was listed in the Orange Book.

39. On information and belief, Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will actively induce and contribute to the actual infringement of the '453 patent.

40. On information and belief, Defendants know or should know that their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will be especially made for or especially adapted for use in infringement of the '453 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will actively contribute to the actual infringement of the '453 patent.

41. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

**Count II**

**(Declaratory Judgment of Infringement of the '453 Patent under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution)**

42. Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

43. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

44. There is an actual case or controversy such that the Court may entertain

Allergan's request for declaratory relief consistent with Article III of the United States

Constitution, and that actual case or controversy requires a declaration of rights by this Court.

45. Defendants have actual knowledge of the '453 patent.

46. On information and belief, Defendants became aware of the '453 patent no later than the date on which that patent was listed in the Orange Book.

47. On information and belief, Defendants have acted with full knowledge of the '453 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '453 patent.

48. The commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will induce the actual infringement of the '453 patent.

49. On information and belief, Defendants know or should know that their commercial manufacture, use, sale, offer for sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will actively induce the actual infringement of the '453 patent.

50. On information and belief, Defendants will encourage another's infringement of the '453 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, which is covered by the claims of the '453 patent.

51. Defendants' acts of infringement will be done with knowledge of the '453 patent and with the intent to encourage infringement.

52. The foregoing actions by Defendants will constitute active inducement of infringement of the '453 patent.

53. On information and belief, Defendants know or should know that their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will be especially made or especially adapted for use in an infringement of the '453 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

54. The commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will contribute to the actual infringement of the '453 patent.

55. On information and belief, Defendants know or should know that their offer for sale, sale and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will contribute to the actual infringement of the '453 patent.

56. The foregoing actions by Defendants will constitute contributory infringement of the '453 patent.

57. On information and belief, Defendants intend to, and will, actively induce and contribute to the infringement of the '453 patent when ANDA No. 91-087 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

58. Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic

Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution by Defendants will induce and/or contribute to infringement of the '453 patent.

59. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, which will actively induce and/or contribute to infringement of the '453 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

60. Unless Defendants are enjoined from actively inducing and contributing to the infringement of the '453 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

61. On information and belief, despite having actual notice of the '453 patent, Defendants continue to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '453 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

#### **Jury Trial Demand**

Pursuant to Federal Rule of Civil Procedure 38(b), Allergan hereby demands a trial by jury of all issues so triable.

#### **Prayer for Relief**

Allergan respectfully prays for the following relief:

a. That judgment be entered that Defendants have infringed the '453 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will constitute an act of infringement of the '453 patent;

b. That judgement be entered declaring that the '453 patent remains valid and enforceable;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Defendants' ANDA shall be a date which is not earlier than the expiration date of the '453 patent, as extended by any applicable period of exclusivity;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '453 patent;

e. If Defendants attempt to engage in the commercial manufacture, use, offer to sell, sale or importation of Defendants' generic product disclosed in their ANDA prior to the expiration of the '453 patent, as extended by any applicable period of exclusivity, a preliminary injunction be entered enjoining such conduct;

f. If Defendants attempt to engage in the commercial manufacture, use, offer to sell, sale or importation of Defendants' generic product disclosed in their ANDA prior to the expiration of the '453 patent, as extended by any applicable period of exclusivity, judgment awarding Allergan damages resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

g. That a declaration be issued under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other

persons acting or attempting to act in active concert or participation with them or acting on their behalf engage in the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, it will constitute an act of infringement of the '453 patent;

h. That this is an exceptional case under 35 U.S.C. § 285, and that Allergan be awarded reasonable attorneys' fees and costs;

i. An accounting for infringing sales not presented at trial and an award by the court of additional damages for any such infringing sales; and

j. That this Court award such other and further relief as it may deem just and proper.

Dated: October 30, 2017

Respectfully submitted,

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Liza M. Walsh

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SALES, LLC

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 401**

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: October 30, 2017

Respectfully submitted,

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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SALES, LLC

**RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, inter alia, injunctive relief.

Dated: October 30, 2017

Respectfully submitted,

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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